IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
Galveston Division

TEXAS DEPARTMENT OF CRIMINAL JUSTICE, Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION et al., Defendants.	)	Civil Action No. 3:17-cv-00001

MEMORANDUM IN SUPPORT OF PLAINTIFF TEXAS DEPARTMENT OF CRIMINAL JUSTICE'S MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

In this case, the Texas Department of Criminal Justice ("TDCJ") challenges an order of the U.S. Food and Drug Administration ("FDA") prohibiting TDCJ from importing a drug to administer lawful capital sentences, through lethal injection. FDA reached beyond its federal public-health charter when it interfered with this core state law-enforcement function. As FDA has previously conceded, "[r]eviewing substances imported or used for the purpose of state-authorized lethal injection clearly falls outside of FDA's explicit public health role." (AR 102.)

The FDA order challenged here rests on two faulty legal claims. *First*, FDA asserts that the drugs violate a statutory provision requiring usage directions that a lay person could follow to self-medicate. The agency has adopted a sensible exemption to that requirement in the "law enforcement" context, where such directions are not necessary to protect the public health. The disputed drugs fall squarely within this law enforcement exemption.

Second, FDA claims that TDCJ cannot receive and use the drugs unless a consensus of experts concludes that they are "safe and effective" for lethal injection, or unless FDA reviews and approves the drugs as "safe and effective" for that same purpose. FDA's assertion that a death penalty agent must be cleared as safe and effective clashes both with the governing statute's plain meaning and with common sense.

The Court should hold that the disputed drugs are lawful imports and order their release to TDCJ.

NATURE AND STAGE OF THE CASE, ISSUES, AND STANDARD OF REVIEW

The parties are presenting the merits for decision through cross-motions for summary judgment.

The issues presented are:

1. Whether the disputed drugs fall within a "law enforcement" exemption to a statutory requirement that otherwise requires usage directions for lay users; and

2. Whether statutory premarket approval requirements apply to the disputed drugs.

The issues presented are pure questions of law involving interpretations of statutes and regulations. We explain below, in section IV, why the Court should interpret those provisions *de novo*, without according any judicial deference to FDA's interpretations.

STATUTORY AND REGULATORY BACKGROUND

A. FDA's Approval Process For "New Drugs"

The Federal Food, Drug, and Cosmetic Act ("FFDCA") requires FDA approval before pharmaceuticals known as "new drugs" may be distributed in interstate commerce. 21 U.S.C. § 355(a). FDA approves marketing of brand-name (innovator) "new drugs" following review of a New Drug Application ("NDA"). Among other things, an NDA includes information about the drug's ingredients, substantial data from clinical studies and animal tests, and descriptions of how the drug is manufactured, processed, and packaged. *Id*. § 355(b). FDA generally approves marketing of generic "new drugs" following review of a more limited Abbreviated New Drug Application ("ANDA"). An ANDA applicant relies upon FDA's prior NDA approval of the name-brand counterpart

to the generic drug under review, supplemented with additional information specific to the generic version of the drug. *Id*. § 355(j)(2)(A).

FFDCA premarket approval requirements apply only to "new drugs" as the statute defines that term. A "new drug" is a drug that (1) is not "generally recognized" by qualified experts as "safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof"; or (2) has become "so recognized" as a result of certain investigations, but which has not, other than in those investigations, been used to a material extent or for a material time under "such conditions." 21 U.S.C. § 321(p). The FFDCA defines "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).[1]

Determining a drug's "new drug" status based on the specific uses claimed in its labeling is a fundamental foundation of the FFDCA's drug approval regime. A drug may be "generally recognized as safe and effective" for some uses but not for others. *See, e.g*., 21 C.F.R. § 330.1(c)(2). Labeling statements identify the uses for which FDA approval is required (absent general recognition of safety and effectiveness for such uses). The statutory approval standards for NDAs and ANDAs therefore directly parallel the statutory definition for a "new drug." FDA approves an NDA if a brand-name drug is proven to be safe and effective under the conditions "prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. §§ 355(d)(1), (d)(5). FDA

[1] In the interest of brevity we use the term "generally recognized as safe and effective" to refer to drugs that are not "new drugs."

approves an ANDA only if the agency has previously approved (for the counterpart brand-name drug) "the conditions of use prescribed, recommended, or suggested in the labeling proposed" for the generic drug. *Id*. § 355(j)(2)(A)(i), (j)(4)(B).

B. Drugs That May Be Lawfully Marketed Without FDA Premarket Approval

A drug that does not meet the statutory definition of a "new drug" may be marketed lawfully without prior FDA approval. One way in which FDA has determined that drugs are not "new drugs" is through the over-the-counter ("OTC") monograph process. *See* 21 C.F.R. § 330. Monographs are FDA regulations establishing standards by which drugs in numerous therapeutic categories are considered generally recognized as safe and effective. *See generally* 21 C.F.R. §§ 331-358. Monographs establish specific criteria (such as particular active ingredient concentrations, directions for use, and warnings) necessary for the drugs to be generally recognized as safe and effective. In developing these regulations, FDA convenes advisory review panels to study clinical data and other information. FDA also receives public comment on the proposed monographs before issuing them in final regulations. If a particular manufacturer's drug complies with the monograph, it is generally recognized as safe and effective *per se*, even if the manufacturer has not performed clinical studies evaluating its own product. *See* 21 C.F.R. § 330.1.

The FFDCA also does not require premarket approval of a drug if it has *no* conditions of use prescribed, recommended, or suggested in the drug's labeling. It is not possible to establish that such a drug is a "new drug," because there are no conditions of

use prescribed, recommended, or suggested in the labeling that could be evaluated for general recognition of safety and effectiveness. In this case, TDCJ maintains that its import is not a "new drug" — and therefore not subject to FDA premarket approval — because there are no conditions of use prescribed, recommended, or suggested in the drug's labeling.

C. The "Adequate Directions For Use" Requirement and the Law Enforcement Exemption

If FDA wants to control drugs with no conditions of use prescribed, recommended, or suggested in their labeling, the agency can invoke requirements other than the premarket approval process. One such requirement is 21 U.S.C. § 352(f)(1), which states that a drug is "misbranded," and therefore unlawful, "unless its labeling bears adequate directions for use." "Adequate directions for use" are those "under which the layman can use a drug." 21 C.F.R. § 201.5. A drug that has no conditions of use prescribed, recommended, or suggested in its labeling generally lacks adequate directions for use, among other things because the drug's labeling omits "[s]tatements of all conditions, purposes, or uses for which such drug is intended." *Id*. § 201.5(a).

Section 352(f)(1) authorizes FDA to promulgate regulations exempting drugs from the "adequate directions for use" labeling requirement if such directions are "not necessary for the protection of the public health." FDA has exempted many categories of drugs from the "adequate directions for use" requirement. One exemption governs "[d]rugs for use in teaching, law enforcement, research, and analysis." 21 C.F.R. § 201.125. In this case, TDCJ maintains that the disputed drugs fall within that

exemption, which applies to drugs that are "shipped or sold to . . . persons . . . engaged in law enforcement, . . . and [are] to be used only for such . . . law enforcement." *Id*.

D. FDA's Process For Refusing Admission Of Imports into Domestic Commerce

The FFDCA establishes a regime in which FDA and the U.S. Bureau of Customs and Border Protection ("Customs") work together to admit into domestic commerce (or refuse admission of) drugs that are offered for import. The FFDCA gives Customs authority to collect samples of drugs offered for import and deliver them to FDA, at FDA's request. 21 U.S.C. § 381(a). In practice, Customs has delegated this sample-collection authority to FDA. FDA collects, and then conducts an "examination" of, the samples to determine whether the agency should refuse the drugs' admission into domestic commerce. 21 U.S.C. § 381(a). The statute allows FDA to refuse admission of a drug, among other things, if it "appears from the examination of such samples or otherwise" that the drug violates the premarket approval requirements of 21 U.S.C. § 355 or the misbranding requirements of 21 U.S.C. § 352(f)(1). *Id*. § 381(a)(3).

If FDA's examination indicates that the drugs should be refused, the agency gives their owner or consignee notice and an opportunity for an informal hearing. 21 U.S.C. § 381(a); 21 C.F.R. § 1.94(a). Following the hearing, FDA's decision to refuse or release the drugs is FDA's final agency action regarding admissibility of the import.

STATEMENT OF FACTS

A. The Drugs Offered For Import

Thiopental sodium is a barbiturate that produces anesthesia and unconsciousness. (AR 111.) This effect is well known; the drug has been used for anesthesia since before Congress enacted the FFDCA in 1938. (AR 118.) Hospitals have used thiopental sodium for decades as a prescription anesthetic. (AR 123-125, 132.) For many years, numerous jurisdictions also have used thiopental sodium (alone or in combination with other drugs) to impose capital sentences through lethal injection. (AR 13.)

TDCJ has previously purchased and used thiopental sodium in executions, before it became commercially unavailable from domestic sources. Through the import at issue in this case, TDCJ is attempting once again to utilize thiopental sodium for purposes of imposing lawful capital sentences. (AR 83.)

Each vial of drug offered for import by TDCJ and at issue in this case bears a label identifying the drug as thiopental sodium and containing the legend: "For law enforcement purpose only." There are no statements in the drug's labeling addressing the drug's conditions of use. (AR 56.)

B. FDA's Detention Of the Thiopental Sodium And TDCJ's Response

On July 24, 2015, a foreign distributor shipped 1000 vials of thiopental sodium, via air freight, to TDCJ. (AR 61.) FDA promptly detained and examined the goods at the border. (AR 71-72.) On August 24, 2015, FDA issued a notice formally alleging that the drugs appear to: "(1) lack adequate directions for use" in violation of 21 U.S.C. § 352(f)(1); and (2) "be a new drug without an approved new drug application" in

violation of 21 U.S.C. § 355(a). (AR 44-47.) The notice gave TDCJ the opportunity for an informal hearing required by statute and regulation.[2]

With TDCJ's consent, FDA conducted the hearing through written submissions. In its first submission (in October 2015), TDCJ presented arguments and evidence that the drugs do not violate the "adequate directions for use" requirement of 21 U.S.C. § 352(f)(1), because the drugs fall within the "law enforcement" exemption to that requirement established by 21 C.F.R. § 201.125. TDCJ also presented arguments and evidence that the drugs do not violate the drug approval requirements of 21 U.S.C. § 355(a), because the drugs are not "new drugs," given that there are no conditions of use prescribed, recommended, or suggested in their labeling. (AR 33-146.)

In April 2016, FDA issued a Tentative Decision that rejected all of TDCJ's arguments. (AR 226-243.) The following month, TDCJ responded to the Tentative Decision with additional arguments and evidence. (AR 246-302.) Another seven months passed. FDA did not render a final decision on the import by the end of 2016.

C. This Case

TDCJ filed this action on January 3, 2017, under the Administrative Procedure Act ("APA"), challenging the agency's decision-making delay. The following month, FDA announced that it would issue its final decision by April 20, 2017. On that date, FDA refused the import, and the Acting Director of FDA's Southwest Import District Office

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[2] The notice alleged an additional misbranding violation under 21 U.S.C. § 352(f)(2). Following submissions by TDCJ, FDA did not include this claim in the final decision refusing the import. That claim therefore is not at issue in this case.

sent a letter to TDCJ stating the rationale for the decision. That letter rejected TDCJ's arguments, concluding that the drugs are misbranded and unapproved new drugs that allegedly violate 21 U.S.C. §§ 355 and 352(f)(1). (AR 5-30.)[3]

TDCJ then amended its complaint to assert new APA claims challenging FDA's final decision on the merits. This summary judgment motion followed.

SUMMARY OF THE ARGUMENT

The statutory "adequate directions for use" requirement does not apply to the disputed drugs, because they fall within the regulatory exemption for law enforcement. The plain language of that exemption applies to lethal injection, which is an aspect of the law enforcement process. The syntax and punctuation of the regulation's text preclude FDA's effort to limit the exemption to law enforcement that does not involve "clinical use." And in any event, lethal injection is not a "clinical use" of the disputed drugs. FDA also fails in its effort to limit the exemption to law enforcement scenarios that existed in 1956, when the regulation was promulgated. A regulation's reach is not limited to applications that existed, or could have been envisioned by an agency, at the time it promulgated the regulation. The Court should adopt TDCJ's interpretation of the exemption and refuse to accord judicial deference to FDA's interpretation.

In addition, premarket approval requirements only apply to "new drugs." A drug is a "new drug" if it is not generally recognized as safe and effective for conditions of use "prescribed, recommended, or suggested" in its labeling. Because the disputed drugs'

[3] We refer to the Acting District Director's letter below as the "refusal decision."

labeling does not state any conditions of use, it is not possible to establish that they are "new drugs," and premarket approval requirements do not apply.

FDA's contrary arguments turn on the premise that the disputed drugs' labeling "hints" at a lethal injection use and the truism that the drugs are not generally recognized as "safe and effective" for that specific use. The labeling does not "hint" at such a use, and if it did, the use would not be "prescribed, recommended, or suggested" in the labeling within the meaning of the statute. FDA's interpretation also leads inevitably to the implausible conclusion that the medical literature must be searched for clinical studies that evaluate the disputed drugs' safety and effectiveness as a death penalty agent. Congress could not have intended such a bizarre result. FDA's interpretation also conflicts with the intent of Congress, as expressed in other statutes, to defer to state-law capital punishment procedures. The Court should adopt TDCJ's interpretation of the statute and refuse to accord judicial deference to FDA's interpretation.

ARGUMENT

I. THE DISPUTED DRUGS ARE NOT MISBRANDED, BECAUSE THEY FALL WITHIN FDA'S REGULATORY EXEMPTION FOR LAW ENFORCEMENT

The disputed drugs are not "misbranded" for failure to have "adequate directions" for lay users in their labeling. 21 U.S.C. § 352(f)(1); 21 C.F.R. § 201.5(a). FDA promulgated a "law enforcement" exemption from this requirement, because in the law enforcement context, self-administration directions for lay users are "not necessary for the protection of the public health." 21 Fed. Reg. 2326, 2327 (Apr. 11, 1956); 21 U.S.C. § 352(f). The law enforcement exemption states:

> A drug subject to § 201.100 or § 201.105, shall be exempt from [21 U.S.C. § 352(f)(1)] if *shipped or sold to, or in the possession of, persons* regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use, or *engaged in law enforcement*, or in research not involving clinical use, or in chemical analysis, or physical testing, *and is to be used only for such* instruction, *law enforcement*, research, analysis, or testing.

21 C.F.R. § 201.125 (emphasis added). The disputed drugs fall squarely within the exemption.

A. The Disputed Drugs Fall Within the Plain Meaning Of the Law Enforcement Exemption

It is axiomatic that the Court should construe the regulatory exemption "to give effect to the natural and plain meaning of its words." *S.D. ex rel. Dickson v. Hood*, 391 F.3d 581, 595 (5th Cir. 2004); *see also United States v. Fafalios*, 817 F.3d 155, 159 (5th Cir. 2016). The plain meaning of the exemption encompasses the disputed drugs.

The drugs were "shipped or sold to" persons at TDCJ, which is an agency "engaged in law enforcement." (AR 58-59, 61, 80, 82-83.) The drugs also are "to be used only for" law enforcement. The restrictive legend on the label ("For law enforcement purpose only") makes that clear. (AR 56; *see also* AR 61, 66-67.)

In addition, the term "law enforcement" means both "the detection and punishment of violations of the law." Black's Law Dictionary 1017 (10th ed. 2014). Capital punishment is an "aspect of the law enforcement process." *Bell v. Lynaugh*, 858 F.2d 978, 986 (5th Cir. 1988) (Jones, J., concurring); *see also Baze v. Rees*, 553 U.S. 35, 61 (2008) (plurality opinion of Roberts, C.J.) (States may enact laws specifying the "sanction" of capital punishment, which is a means to "'enforce'" a State's laws (citation

omitted)). Accordingly, when FDA has discussed lethal injection in the past, the agency has acknowledged that "state Departments of Correction" are engaging in "law enforcement." (AR 102.) TDCJ has confirmed that the drugs are to be used only for the specific law enforcement purpose of effectuating lawfully-imposed capital sentences. (AR 82-83, 301.) TDCJ also has strict security controls to prevent diversion of the drugs to other purposes. (AR 83, 299.)

FDA's decisions in this matter effectively concede that the purpose of the disputed drugs fits within the ordinary meaning of the term "law enforcement." In its April 2015 tentative decision, FDA conceded that, at least "in one sense of" the term, lethal injection is a law enforcement function. (AR 237.) FDA's final refusal decision presents a variety of arguments, but none of them denies that the drugs' purpose is "law enforcement." The Court should hold that the exemption applies, based on the well-established principle that the regulation's "words were meant to express their ordinary meaning." *Bouchikhi v. Holder*, 676 F.3d 173, 177 (5th Cir. 2012); *see also Tilden Mining Co. v. Sec'y of Labor*, 832 F.3d 317, 323 (D.C. Cir. 2016) (regulation applies to situations that "fall within the natural compass" of expansive regulatory term).[4]

[4] For the law enforcement exemption to apply here, the disputed drugs also must be prescription drugs as defined in the FFDCA. In the language of the exemption, the drug must be "subject to § 201.100" — which is a shorthand reference to prescription drugs as they are defined in section 503(b)(1) of the FFDCA. *See* 21 C.F.R. § 201.100 (addressing drugs "subject to the requirements of section 503(b)(1) of the act"). FFDCA section 503(b)(1) (codified at 21 U.S.C. § 353(b)(1)) defines a prescription drug as one "intended for use by man which . . . because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to

B. The Exemption's References To "Clinical Use" Do Not Preclude Application Of the Exemption

FDA's refusal decision relies substantially on a claim that the exemption is limited to law enforcement "not involving clinical use." (AR 23-24.) The Court should reject that claim, based on both the punctuation and structure of the regulatory language. *See, e.g.*, *Elgin Nursing and Rehab. Ctr. v. U.S. Dept. of Health & Human Servs*., 718 F.3d 488, 494 (5th Cir. 2013) (referring to significance of punctuation and structure in regulatory language).

The regulation lists categories of "persons" who may receive, purchase, or possess drugs under the exemption:

> persons regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use, or engaged in law enforcement, or in research not involving clinical use, or in chemical analysis, or physical testing . . . .

21 C.F.R. § 201.125. Two of the categories — regarding "medicine" and "research" — contain the qualifier "not involving clinical use." The other categories — including "law enforcement" — do not. In a series such as this, including the qualifier in some cases and excluding it in others reflects a conscious decision to omit the qualifier where it does not appear. *See, e.g., H.B. Zachry Co. v. Occupational Safety and Health Review Comm'n*, 638 F.2d 812, 817 (5th Cir. 1981). That means that the law enforcement exemption applies regardless of whether "clinical use" occurs.

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administer such drug." 21 U.S.C. § 353(b)(1)(A). FDA concedes that the disputed drugs meet that definition. (AR 20 n. 17.)

The syntax and punctuation of the regulatory language confirm that interpretation. The exemption applies to persons "engaged in" activities regarding "medicine not involving clinical use, or engaged in law enforcement, ..." The commas before and after the phrase "*or engaged in law enforcement*" separate that phrase as a distinct concept, unaffected by the preceding qualifier "*not involving clinical use*." In addition, repeating the phrase "engaged in" a second time — and after the disjunctive term "or" — signifies that the qualifier does not carry over to the "law enforcement" category. *See* Antonin S. Scalia and Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts*, 148 (2012) ("The typical way in which syntax would suggest no carryover modification is that a determiner (*a, the, some, etc.*) will be repeated before the second element."); *Loughrin v. United States*, 134 S. Ct. 2384, 2390 (2014) (ordinary use of the term "or" is that "'the words it connects are to be given separate meanings'" (citation omitted)).[5]

The refusal decision nonetheless speculates that FDA intended to imply the qualifier into all of the categories in which the qualifier is not expressly stated. (AR 23.)

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[5] The history of the regulation also supports the foregoing interpretation. The regulation's original version addressed both drugs and medical devices and did not include the law enforcement exemption. 17 Fed. Reg. 6818, 6819-20 (July 25, 1952). When FDA amended the regulation to add the law enforcement exemption, the agency inserted that new exemption between the "medicine" and "research" categories — both of which contained the qualifier "not for clinical use." But FDA omitted the qualifier from the law enforcement exemption. 21 Fed. Reg. at 2326-27. That omission reflects a conscious decision not to apply the qualifier to the law enforcement exemption. Furthermore, FDA did not change that conscious decision when it later amended the regulation to separate the device exemption into a different regulation. *See* 21 C.F.R. § 801.125. The operative language of the device law enforcement exemption is identical to the operative language of the drug law enforcement exemption — both omit the qualifier "not for clinical use" from the "law enforcement" category. *Compare id*. *with* 21 C.F.R. § 201.125.

The Court should reject FDA's argument, which clashes directly with the well-established "rule of construction that where a term is carefully employed in one place and excluded in another, *it should not be implied where excluded*." *Diamond Roofing Co. v. OSHA*, 528, F.2d 645, 648 (5th Cir. 1976) (emphasis added).[6]

C. The Law Enforcement Exemption Is Not Limited to Law Enforcement Scenarios That Existed in 1956

The refusal decision also argues that the law enforcement exemption could not apply to lethal injection, because states did not use lethal injection in 1956, at the time FDA promulgated the exemption. (AR 23.) The Court should reject FDA's historical argument. Because a regulation's meaning turns on its text, broadly drafted regulations such as this one are *not limited* to applications that existed, or could have been envisioned by an agency, at the time it promulgated the regulation. *See, e.g.*, *Or. Paralyzed Veterans of Am. v. Regal Cinemas, Inc.*, 339 F.3d 1126, 1133 (9th Cir. 2003) (broadly-drafted regulation with a broad purpose "may be applied to a particular factual scenario not expressly anticipated at the time the regulation was promulgated"); *see also Pa. Dep't of Corrs. v. Yeskey*, 524 U.S. 206, 212 (1998) (broadly worded statute "'can be applied in situations not expressly anticipated by Congress'" (citation omitted)); *West v. Gibson*,

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[6] In the alternative, even assuming *arguendo* that the qualifier could be implied into the law enforcement exemption, the disputed drugs would still fit within the exemption. The plain meaning of the term "clinical use" is use involving medical treatment of a patient. *See, e.g.*, Random House Webster's Unabridged Dictionary 387 (2001) (defining "clinical" as "concerned with or based on actual observation of and treatment of disease in patients rather than experimentation or theory"); *see also Sanderson Farms, Inc. v. Perez*, 811 F.3d 730, 736 (5th Cir. 2016) (relying on dictionary to interpret regulatory text). The detained drugs are not for a clinical use within the plain meaning of that term.

527 U.S. 212, 218 (1999) (applying statute to situation not contemplated by Congress because statutory language "does not freeze the scope of" a key word as of the date of enactment); *Consumer Elecs. Ass'n v. FCC*, 347 F.3d 291, 298 (D.C. Cir. 2003) ("evidence of a specific 'catalyz[ing]' force" behind the statute's passage "'does not define the outer limits of the statute's coverage'" (citation omitted)); *KCMC, Inc. v. FCC*, 600 F.2d 546, 549 (5th Cir. 1979) ("[I]n construing a regulation, we must employ the rules of construction generally applicable to statutes.").

If FDA's interpretive approach were correct, the categories in the exemption other than "law enforcement" — regarding pharmacy, chemistry, medicine, chemical analysis, and physical testing — *also* would be restricted to applications that existed when *they* were promulgated in the 1950's. *See* 17 Fed. Reg. at 6819-20. That surely cannot be correct. Given the revolutionary changes in all of these scientific disciplines over the last 60 years, such time-based restrictions would effectively nullify those five categories in the exemption. The Court should reject an interpretation that eviscerates the regulation. *Cf. Citizens Bank of Md. v. Strumpf*, 516 U.S. 16, 20 (1995) (citing "elementary rule of construction" that statute "'cannot be held to destroy itself'" (citation omitted)).

In addition, the contemporaneous regulatory materials from 1956 do not prove FDA's claim that the exemption is limited to law enforcement activities at that time (such as officer training and "undercover buys"). (AR 24.) The claimed limitation to officer training is inconsistent with the exemption's language, which refers to "instruction" with respect to "pharmacy" but not with respect to "law enforcement." 21 C.F.R. § 201.125. And the claimed limitation to "undercover buys" is sheer speculation. The refusal

decision cites no evidence establishing that the agency intended the exemption to protect FDA officials from liability in that context (or that such protection was even necessary).

Finally, to the extent that the Court considers FDA's *actual* contemporaneous statements about the exemption — which the Court need not do — those statements strongly *support* application of the exemption to the disputed drugs. When it promulgated the exemption, FDA determined that otherwise-applicable "adequate directions for use" requirements "are not necessary for the protection of the public health" when law enforcement is involved. 21 Fed. Reg. at 2327. "Adequate directions for use" are obviously unnecessary to protect the public health in the lethal injection context. (*See* AR 102 (reviewing imported drugs with respect to lethal injection "clearly falls outside of FDA's explicit public health role").) In fact, it is hard to understand a justification of any kind for requiring adequate directions for use — which are, by definition, self-administration directions for lay users — in the context of *state-administered* lethal injection.

II. THE DISPUTED DRUGS DO NOT FALL WITHIN THE DEFINITION OF "NEW DRUGS" AND THEREFORE DO NOT VIOLATE PREMARKET APPROVAL REQUIREMENTS

The disputed drugs also do not fall within the statutory definition of "new drugs" and therefore do not violate statutory premarket approval requirements.

A. A Drug Is Not a "New Drug" If It Has No Conditions Of Use "Prescribed, Recommended, or Suggested" in the Labeling

The FFDCA determines which drugs are "new drugs" (subject to premarket approval requirements) based on the specific conditions of use claimed in their labeling.

See supra at 3-4. Accordingly, changes in a drug's labeling can change a product's "new drug" status (and therefore change whether FDA premarket approval is required). A drug that is *not* a "new drug" — because it is generally recognized as safe and effective for the specific conditions of use described in the labeling — *becomes* a new drug if the labeling is changed to state a new use for which the drug lacks such general recognition. 21 C.F.R. § 310.100(c); 65 Fed. Reg. 14,286 (Mar. 16, 2000). The converse also is true. A drug that *is* a new drug *loses* its "new drug" status (and therefore is exempt from premarket approval requirements) if the labeling is changed to state only conditions of use that are generally recognized as safe and effective.

Because "new drug" status is inextricably tied to specific uses stated in the labeling, it is not possible to establish that a drug is a "new drug" if it has *no* conditions of use stated in its labeling. There simply is no way to evaluate general recognition of safety and effectiveness among experts — which is the essence of the "new drug" determination — in the abstract, without focusing on a particular labeled use. *See, e.g.*, 21 C.F.R. § 201.115 (referring to drug that is not a new drug but "would be a new drug if its labeling bore representations for its intended uses").

FDA has other comprehensive regulatory authorities (unrelated to premarket approval) to control unapproved drugs with no uses stated in their labeling. For example, FDA typically may prohibit such drugs under the statute's "misbranding" provisions (which mandate certain *affirmative* labeling statements). 21 U.S.C. § 352. *See, e.g.*, *United States v. Travia*, 180 F. Supp. 2d 115, 116 (D.D.C. 2001) (asserting claims against distributor of drug in unlabeled containers under misbranding prohibitions but not under

premarket approval requirements). The misbranding requirements apply regardless of whether FDA has, or has not, approved a drug and regardless of whether a drug is, or is not, a "new drug." 21 C.F.R. § 314.170.[7]

B. The Disputed Drugs Are Not "New Drugs," Because Their Labeling Does Not "Prescribe, Recommend, or Suggest" Any Condition of Use

The disputed drugs are not "new drugs," because their labeling does not "prescribe, recommend, or suggest" any conditions of use. Conditions of use include the particular medical condition, or indication, to be treated with the drug. *See, e.g.*, *United States v. Rutherford*, 442 U.S. 544, 549 (1979); 42 Fed. Reg. 39,768, 39,792 (Aug. 5, 1977). Labeling includes the drugs' labels. 21 U.S.C. § 321(m). The labels at issue state the drug's name ("Thiopental Sodium"), the descriptive term "Sterile" and the quantity "1 gm." (AR 56.) The labels also identify the distributor and refer to the batch number and manufacturing and expiration dates. (*Id*.) None of these statements is a condition of use.

The labels also contain three legends, each of which addresses a regulatory requirement but does not state a condition of use. The legend "Rx Only" satisfies a labeling requirement that applies to a drug that meets the definition of a prescription drug (regardless of its specific conditions of use). *See* 21 U.S.C. § 353(b)(4)(A). The legend "CIII" satisfies a labeling requirement for a Schedule III controlled substance such as

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[7] Under the particular circumstances of this case, the law enforcement exemption described above prevents applying the only misbranding prohibition that FDA has claimed.

thiopental sodium (regardless of its specific conditions of use). 21 U.S.C. § 825(a); 21 C.F.R. § 1302.03(c). Finally, the legend "For law enforcement purpose only" invokes the regulatory exemption discussed above.[8]

C. FDA Erroneously Determined That the Disputed Drugs Are "New Drugs" Based on Information Outside Of Their Labeling

1. FDA's "New Drug" Determination Was Based on Information Outside the Labeling

The refusal decision concluded that the disputed drugs are "new drugs" on the ground that their labeling allegedly claims a "lethal injection" use — a use for which thiopental sodium is not generally recognized as safe and effective. FDA's decision relied in part on the argument that the labels' references to the name of the drug ("Thiopental Sodium") and the fact that it is "sterile" allegedly indicate a lethal injection use. (AR 13.) As FDA concedes, however, sterile injectable thiopental sodium has been used for decades for a variety of different purposes other than lethal injection. (AR 14; *see also* AR 111, 118, 123-125, 132.) Statements of the drug's name and the fact that it is sterile obviously do not constitute a claim that the drug will be used for lethal injection.

FDA's decision also relied on the argument that the label's reference to the "law enforcement" exemption states a condition of use for lethal injection. The term "law

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[8] There also is no "labeling" outside of the disputed drugs' "label" that states any condition of use. *See* 21 U.S.C. § 321(m) (defining "labeling"). The disputed drugs were not accompanied by any package insert. (AR 589.) The only documentation accompanying the drug includes commercial and customs records identifying the name and quantity of the drug. (AR 58-59.) The customs declaration form for the import reiterates that the drug is for "law enforcement only." (AR 61.)

enforcement" plainly is not a condition of use. In the context discussed in the statute, a condition of use must be capable of being evaluated, by qualified experts, for safety and effectiveness. *See* 21 U.S.C. § 321(p). No such evaluation of "law enforcement" could be conducted.[9] In addition, while lethal injection is one type of "law enforcement," it is not the only type of "law enforcement," as the refusal decision emphasizes. (AR 24.) The reference to law enforcement is not tantamount to a reference to lethal injection.[10]

In fact, the only information that FDA relies upon to demonstrate a lethal injection use is information *outside* of the labeling. That information falls into two categories: (1) court cases and publications indicating that "one of the best-known uses of thiopental sodium is for lethal injection" (AR 13-14); and (2) submissions by TDCJ in the current dispute with FDA indicating that TDCJ intends to use the disputed drugs for lethal injection. (AR 14-15.) Neither category of evidence is labeling, among other things because it is not "upon" the drugs (or their containers or wrappers) and does not "accompany" the drugs. 21 U.S.C. § 321(m). Information *outside* of the labeling that documents an intended use for the drugs is not a condition of use "prescribed,

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[9] If label a referring to "law enforcement" stated a condition of use, then so would a label referring to the other categories listed in the exemption regulation (e.g., instruction in pharmacy, chemistry, or medicine not involving clinical use). That would mean a drug could not be used for those purposes without FDA approval (or studies establishing general recognition of safety and effectiveness for those purposes). But FDA obviously would not approve, and clinicians obviously would not study, a drug for such matters as instruction in pharmacy, chemistry, or medicine not involving clinical use.

[10] The label does not state a condition of use even if the term "law enforcement" is viewed as a warning not to use the drugs for any medical purpose. (*See* AR 14.) A warning not to use the drugs for any medical purpose is not a specific condition of use that could be evaluated for safety and effectiveness.

recommended, or suggested *in* the labeling." 21 U.S.C. § 321(p)(1) (emphasis added). FDA's interpretation therefore conflicts with the plain and unambiguous language of the statute.

2. The Refusal Decision Ignores The Critical Statutory Distinction Between a Drug's "Intended Use" — Which Can Be Established by Information Outside the Labeling — and the Uses "Prescribed, Recommended, or Suggested in the Labeling"

FDA's refusal decision erroneously asserts that it would be ignoring the obvious — and putting blinders on — to limit a "new drug" determination to statements in the labeling when statements outside the labeling document TDCJ's intent to use the drugs for lethal injection. (AR 12-13 n.8.) FDA sidesteps that fact that the premarket approval process is not the agency's only regulatory tool. If FDA wants to address concerns about intended uses stated outside the labeling, the agency must rely on *other* mechanisms in its comprehensive regulatory arsenal. That is because the statute's plain and unambiguous language inextricably ties premarket approval requirements to statements in the labeling (regardless of what information outside the labeling may indicate about intended use).[11]

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[11] If a drug is promoted for intended uses not stated in the labeling, FDA typically claims that the drug lacks adequate directions for that use (and therefore is misbranded under 21 U.S.C. § 352(f)(1)). *See* Coleen Klasmeier & Martin H. Redish, *Off-Label Prescription Advertising, the FDA and the First Amendment: A Study in the Values of Commercial Speech Protection*, 37 Am. J. Law & Med. 315, 320 & n.21 (2011). That is because FDA's "adequate directions for use" regulations require that labeling must include statements of all intended uses. *See supra* at 5 (citing 21 C.F.R. § 201.5(a)). Here the law enforcement exemption precludes application of that misbranding prohibition.

FDA *can* claim a violation of the statutory premarket approval requirements if an FDA-approved new drug is promoted for intended uses not stated in the FDA-approved labeling, as long as that promotion occurs through statements in other materials that accompany the drug (and therefore meet the statutory definition of "labeling"). But that

FDA's own regulations confirm that uses that are intended — but not stated in the labeling — are not a basis for establishing that a drug is a "new drug." 21 C.F.R. § 201.115 (describing a drug that is not a new drug even though it "*would be a new drug if its labeling bore representations for its intended uses*" (emphasis added)). This distinction between an *intended* use and a *labeled* use is an important one, and it stems directly from the statute's text. The FFDCA generally defines the term "drug" with respect to an article's intended use and does not impose limitations on how that intended use may be proved. 21 U.S.C. §§ 321(g)(1)(B), (g)(1)(C). Accordingly, information outside the labeling may be considered to establish that an article is a "drug" in the first place. But in stark contrast, as explained above, determination of "new drug" status is strictly limited to uses specifically stated in the labeling.[12]

This is not the first time that FDA has erroneously overlooked this important statutory distinction between intended uses (provable by evidence outside labeling) and uses "prescribed, recommended, or suggested in" labeling. In *Association of American Physicians*, 226 F. Supp. 2d. 204, the court evaluated an FDA statutory interpretation

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"theory would apply only where the off-label statement occurs in a communication that qualifies as 'labeling' under the [F]FDCA." Klasmeier & Redish, 37 Am J. Law & Med. at 319-20 & n.20. The reason is that the new drug approval requirements are inextricably tied to statements in labeling.

[12] FDA also has promulgated a regulation that states a definition of "intended uses" relating to certain "misbranding" provisions. Under that regulation, proof of an intended use can extend to information outside of the labeling. 21 C.F.R. § 201.128. The "intended use" definition in this misbranding regulation has no application to the entirely separate question whether a "drug" is a "new drug." *See Ass'n of Am. Physicians and Surgeons, Inc. v. FDA*, 226 F. Supp. 2d. 204, 215 n.17 (D.D.C. 2002) (refusing to apply "intended use" definition of 21 C.F.R. § 201.128 when determining uses "prescribed, recommended, or suggested in" labeling).

asserting that uses "suggested" in a drug's proposed labeling included uses that were "likely" or "foreseeable" (based on information outside the labeling). *Id*. at 215. The court rejected FDA's interpretation, in part because it did not recognize the distinction between "intended use" and uses "prescribed, recommended, or suggested in" proposed labeling:

> Here, we are not determining whether something is a drug; we are looking to a different section of the FDCA entirely. And this section requires that a drug be safe and effective for those uses 'prescribed, recommended, or suggested *in the proposed labeling*.' § 355(d).

Id. at 216. This Court should similarly hold that evidence outside the disputed drugs' labeling is not pertinent to a "new drug" determination.

D. A Use That the Labeling Indirectly "Hints" At Is Not "Prescribed, Recommended, or Suggested" Within the Meaning Of the Statute

In *Association of American Physicians*, the court also rejected as erroneous — and even derided as "unfortunate" — an FDA statutory interpretation claiming that a use can be "suggested" in a drug's labeling even if the use "is not expressly recommended or is even disclaimed." 226 F. Supp. 2d. at 215 & n.16; *id*. at 217. FDA's refusal decision makes a similar argument that the term "suggested" includes a use not affirmatively stated but merely "hinted" at. (AR 12.) The Court should reject FDA's argument.

1. A Use Must Be Stated Affirmatively To Be "Prescribed, Recommended, or Suggested"

The disputed drugs' labeling does not include "hints" of a lethal injection use; all of the information regarding lethal injection is outside the labeling. *See supra* at 20-21. But even if the labeling did "hint at" a lethal injection use, that use would not be

"prescribed, recommended, or suggested in the labeling" within the meaning of the statute.

The statutory phrase "prescribed, recommended, or suggested" is straightforward and unambiguous. The court should "'assume that the ordinary meaning of that language accurately expresses the legislative purpose.'" *Hardt v. Reliance Standard Life Ins. Co*., 560 U.S. 242, 251 (2010) (citation omitted); *BMC Software, Inc. v. C.I.R.*, 780 F.3d 669, 674 (5th Cir. 2015) (same). "Prescribe" means "to lay down, in writing or otherwise, as a rule or a course of action to be followed." Random House Webster's Unabridged Dictionary 1529 (2001). "Recommend" means "to represent or urge as advisable or expedient." *Id*. at 1012. And "suggest" means "to mention or introduce (an idea, proposition, plan, etc.) for consideration or possible action." *Id*. at 1902. The Fifth Circuit has referred to the entire phrase — "prescribed, recommended, or suggested in the labeling" — as "the uses described in its labeling." *United States v. Articles of Drug*, 625 F.2d 665, 670 & n.9 (5th Cir. 1980) (citing 21 U.S.C. § 321(p)). FDA's regulations similarly indicate that "new drug" status turns on "representations" in the labeling about a drug's uses. 21 C.F.R. § 201.115. In sum, for a use to be "prescribed, recommended, or suggested" in the labeling, it must be affirmatively stated in the labeling.

2. FDA's Interpretation Is Foreclosed By Other Statutory Provisions That Address Uses "Prescribed, Recommended, or Suggested" In Labeling

FDA premises its statutory interpretation on a single dictionary definition (of the

term "suggested") that differs from the definition cited above.[13] The parties' competing dictionary definitions therefore cannot resolve the meaning of the term "suggested." To interpret that term, the Court must construe the statutory phrase "prescribed, recommended, or suggested" in context, with a view to its place in the overall statutory scheme. *Roberts v. Sea-Land Servs., Inc*., 566 U.S. 93, 101 (2012); *Contender Farms, L.L.P. v. U.S. Dep't of Agric.*, 779 F.3d 258, 269 (5th Cir. 2015) ("[W]e read the statute's words in proper context and consider them based on the statute as a whole."). Reading the term "suggested" in context forecloses FDA's interpretation.[14]

It is well established that "identical words and phrases within the same statute should normally be given the same meaning." *Powerex Corp. v. Reliant Energy Servs., Inc*., 551 U.S. 224, 232 (2007); *Fontenot v. Watson Pharms., Inc.*, 718 F.3d 518, 521 (5th Cir. 2013) (same). Following that rule, the *Association of American Physicians* court has specifically confirmed that the phrase "prescribed, recommended, or suggested" means the same thing each time it appears in the various statutory provisions governing new

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[13] FDA cites a dictionary for the proposition that "suggest" means arousing or awakening, often by "indirect means," or to mention as a "hint." (AR 12.) But the very same dictionary also defines "suggest" as an affirmative proposal: "[t]o say or advance by way of a suggestion." (AR 311.) The second definition in FDA's dictionary is consistent with the dictionary definition that TDCJ cites above.

[14] The fact that there are two competing dictionary definitions does not make the term "suggested" ambiguous. "Ambiguity is a creature not of definitional possibilities but of statutory context." *Brown v. Gardner*, 513 U.S. 115, 118 (1994). A term can have multiple different meanings in the abstract but be unambiguous when construed in context. *See, e.g., HolRail, LLC v. Surface Transp. Bd*., 515 F.3d 1313, 1317 (D.C. Cir. 2008) (term "cross" was unambiguous in context even though it "may have multiple meanings in some circumstances"). In context, the term "suggested" is unambiguous, as explained below. We further explain below, in section IV, why this lack of ambiguity forecloses judicial deference to FDA's statutory interpretation.

drug approvals:

> The applicability of the above provisions [governing new drug approvals] all turns on what is '*prescribed, recommended, or suggested*' in a product's labeling. Thus, the import of those three words must be scrutinized, and the analysis may apply to all.

226 F. Supp. 2d. at 214-15.

Each time the statute repeats this critical phrase, it means a use affirmatively and unambiguously stated in the labeling (and *not* a use indirectly "hinted" at). *First*, applicants seek FDA approval for the specific uses that are "prescribed, recommended, or suggested in the proposed labeling" of a drug. *See* 21 U.S.C. §§ 355(d)(1), (d)(5), *id*. § 355(j)(2)(A)(i). The requested approval is for uses that the proposed labeling states expressly and unambiguously. An application for approval "must identify the particular use or uses to which the new drug will be put, and an approval of such an application for interstate distribution can become effective only with respect to such use(s)." 65 Fed. Reg. at 14,286; *see also* 21 C.F.R. § 314.50(c)(2)(i) (application must include "proposed labeling" and annotations to information that "support[s] the inclusion of each statement in the labeling"). Applicants do not simply "hint" at the uses for which they seek FDA approval.

Second, when NDA applicants submit studies to support approval, the studies must prove that that the drug is effective for those very same expressly stated, unambiguous uses that are "prescribed, recommended, or suggested in the labeling or proposed labeling." *Id*. § 355(d)(7). NDA applicants also must submit studies that "demonstrate that the product is safe 'for use under the conditions prescribed,

recommended, or suggested in the proposed labeling thereof.'" *Ass'n of Am. Physicians*, 226 F. Supp. 2d. at 214 (citing 21 U.S.C. § 355(d)(1)). "When the FDA approves a drug, it approves the drug only for the particular use for which it was tested . . . ." *Id*. at 206. NDA applicants do not pursue clinical studies and other scientific investigations of uses that are simply "hinted" at rather than clearly defined.

Third, when FDA approves a drug, the approval only covers the conditions of use "prescribed, recommended, or suggested" in the approved drug's labeling. 21 U.S.C. §§ 355(d)(1), (d)(5), *id*. § 355(j)(2)(A)(i); *see also Am. Pharm. Ass'n v. Mathews*, 530 F.2d 1054, 1055 (D.C. Cir. 1976) (McGowan, J., concurring) (recognizing as "pivotal" the approval of a new drug "'under the conditions prescribed, recommended, or suggested in the proposed labeling thereof'" (citing 21 U.S.C. § 355(d))). The approved uses are not simply "hinted" at. There is absolutely no ambiguity about the uses that FDA has approved, because the approval covers "the exact text in the proposed label." *Wyeth v. Levine*, 555 U.S. 555, 568 (2009) (citing 21 U.S.C. § 355; 21 C.F.R. § 314.105(b)). The label and the approval are so inextricably intertwined that the approved uses also are known as "labeled use[s]." 65 Fed. Reg. at 14,286. By contrast, "[a] use that does not appear in the labeling is not approved as safe and effective by FDA and is known as an 'unapproved' or 'off-label' use." *Id*.

A bright-line statement of the approved uses "prescribed, recommended, or suggested" in the labeling is absolutely critical under the FFDCA drug approval regime, because promotion of a new drug for other (unapproved) uses can carry serious legal consequences. A "central feature of the [F]FDCA is that it generally prohibits interstate

commerce in new drugs" for unapproved uses. *Id*. The government "has repeatedly prosecuted — and obtained convictions against — pharmaceutical companies and their representatives . . . based on their off-label promotion." *United States v. Caronia*, 703 F.3d 149, 154 (2d Cir. 2012) (citing cases); *see also supra* at 22-23 n.11 (discussing legal claims available to the government).

Finally, the FFDCA uses the identical statutory phrase in provisions governing critical safety and effectiveness determinations about other FDA-regulated products: medical devices[15] and animal drugs.[16] These provisions corroborate that uses "prescribed, recommended, or suggested in the labeling" of a product are well-defined and affirmatively and unambiguously stated, not indirectly "hinted" at.[17]

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[15] *See, e.g.,* 21 U.S.C. § 360c(a)(2)(B) (determining safety and effectiveness of devices "with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device"); *id*. §§ 360c(a)(3)(A), (a)(3)(B)(ii) (requiring demonstration of effectiveness of device "under the conditions of use prescribed, recommended, or suggested in the labeling of the device"); *id*. §§ 360e(e)(1)(A), (e)(1)(B) (addressing withdrawal of marketing approval if device is not safe or effective "under the conditions of use prescribed, recommended, or suggested in the labeling thereof").

[16] *See, e.g.,* 21 U.S.C. § 360b(2)(A)(viii) (prohibiting approval of animal drug if inactive ingredients are unsafe "under the conditions prescribed, recommended, or suggested in the labeling"); *id*. § 360b(d)(1)(F) (prohibiting approval of animal drug if a "use prescribed, recommended, or suggested in labeling" will result in an unsafe residue); *id*. § 360b(d)(3) (requiring that studies supporting animal drug approval prove effectiveness "under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof").

[17] The present case is distinguishable from *Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013). That case addressed the question whether FDA had discretion to admit an import of unapproved thiopental sodium with labeling that *did* prescribe, recommend, or suggest specific conditions of use: "general anesthesia," "convulsive disorders," and "intracranial pressure." (AR 290-293.) In the District Court, the parties evidently agreed that there was no general acceptance of safety and effectiveness for those labeled uses, because the parties *did not dispute* that the drugs were unapproved new drugs that violated the FFDCA. *Beaty v. FDA*, 853 F. Supp. 2d 30, 34 n.2 (D.D.C. 2012), *aff'd in part, vacated*

E. An Absence of Published Studies Regarding a Specific Company's Drug Does Not Automatically Make It a "New Drug"

The refusal decision also argues that the disputed drugs cannot possibly be generally recognized as safe and effective for any use, because the agency cannot find any published clinical studies involving thiopental sodium that was manufactured and distributed by the specific companies that supplied TDCJ. (AR 17.) That argument fails, because there is no statutory requirement that a particular company must always conduct published clinical studies of its own product in order for it to be generally recognized as safe and effective. Other companies' studies of the same drug may suffice. Therefore FDA's inability to find published studies from the disputed drugs' manufacturer and distributor does not automatically establish that the drugs are "new drugs."

FDA's argument relies heavily on the Supreme Court's statement, in *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973), that general recognition of effectiveness requires at least "substantial evidence" of effectiveness such as that required "for approval of an NDA." *Id*. at 629.[18] The refusal decision extrapolates from this statement about NDA approval standards. FDA argues that because a particular company typically must study its own drug for an NDA to be approved, a particular

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in part, Cook, 733 F.3d 1. The only issue in *Cook/Beaty* was whether FDA had discretion to admit these *concededly* violative drugs into domestic commerce. In stark contrast, the question in this case is whether the drugs violate the statute in the first place; FDA's discretionary authority to admit drugs proven to be violative is not presented here.

[18] This statement was limited to evidence of effectiveness and did not apply to evidence of safety; the statutory provision requiring "substantial evidence" for NDA approvals only applies to effectiveness, not safety. *Id*. at 630; *see also* 21 U.S.C. § 355(d).

company also allegedly must study its own drug for it to be generally recognized as safe and effective. FDA reads too much into the Supreme Court's statement. In discussing "substantial evidence," the Court was addressing the fact that "adequate and well controlled investigation[s]" to establish effectiveness are necessary, and that "anecdotal" evidence, "uncontrolled studies," or "partially controlled studies" will not suffice. *Id*. at 629-30. The Court did not hold that such adequate and controlled investigations always must address a specific company's product — as opposed to an analogous product from another company — to establish general recognition.

The refusal decision itself indicates that published studies regarding one company's product can establish general recognition of safety and effectiveness for a different company's version of the same drug, as long as additional studies confirm that both companies' products are bioequivalent. (AR 18-19.) Assuming *arguendo* that the refusal decision is correct on that point, such bioequivalence studies are proprietary endeavors rarely (if ever) published in the scientific literature. FDA has no way to find such studies through a literature search. FDA therefore also has no way of knowing, through a literature search, whether the disputed drugs are generally recognized as safe and effective for an identified use, based on unpublished bioequivalence studies coupled with published safety and effectiveness studies regarding another company's thiopental sodium.[19]

[19] The entire generic drug approval process rests on the analogous conclusion that an ANDA applicant does not need to repeat safety and effectiveness studies performed on the corresponding brand-name drug and can obtain FDA approval, among other things,

Furthermore, in *Hynson, Westcott & Dunning*, the Supreme Court's cross-reference to NDA approvals did not hold that every single evidentiary requirement for such approvals applies to a determination regarding general recognition of effectiveness. In fact, in a companion case issued the same day — and authored by the same Justice — the Supreme Court expressly confirmed that "in some cases general recognition that a drug is efficacious might be made *without* the kind of scientific support necessary to obtain approval of an NDA." *Weinberger v. Bentex Pharms., Inc*., 412 U.S. 645, 652-53 (1973) (emphasis added). *Bentex* also discussed the OTC monograph process (*id*. at 650-51), which is a specific situation in which a particular company's product does not need to be studied for it to be generally recognized as safe and effective. These monographs define general recognition of safety and effectiveness for certain drugs by regulation. *See supra* at 4. The expert panels that develop the monographs do not study every single company's product that will be deemed generally recognized as safe and effective under the monograph.[20] And if a particular company's version of a drug complies with a final monograph, the drug is generally recognized as safe and effective without having been studied at all.[21]

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by conducting proprietary studies assuring that the generic and brand-name drugs are bioequivalent. *See* 21 U.S.C. § 355(j)(2)(A)(iv).

[20] *Cf*. 37 Fed. Reg. 85, 86 (Jan. 5, 1972) (noting that there were "100,000 to one-half million" OTC drugs on the market and for many of these drugs, "the labeling is similar and the active ingredients are the same, or essentially the same, but are present in slightly different dosages. Although each is a separate product, the same scientific and medical evidence is relevant in reviewing all OTC drugs within a given therapeutic class").

[21] The OTC monograph process also demonstrates that a drug can be generally recognized as safe and effective regardless of whether there is proof that that

Because general recognition of safety and effectiveness for a particular company's product does not always depend on published studies of that specific product, FDA's medical literature search does not establish that the disputed drugs are "new drugs."

III. FDA'S INTERPRETATION OF THE STATUTE CONFLICTS WITH OTHER INDICIA OF CONGRESSIONAL INTENT

A. FDA's Statutory Interpretation Leads to Bizarre Results That Congress Could Not Have Intended

FDA's statutory interpretation concludes that the disputed drugs are labeled for a lethal injection use. That conclusion leads automatically to the question whether published clinical studies demonstrate the drugs' safety and effectiveness for that specific use. Therefore to support the agency's interpretation, a senior FDA medical officer actually searched the medical literature to see whether he could find human studies assessing thiopental sodium's safety and effectiveness for lethal injection. (AR 639-640 (using the search terms "lethal injection," "capital punishment," "execution," and "euthanasia" to search for lethal injection clinical studies in medical literature database).) He predictably found none. FDA then reached the decision that the disputed drugs are not generally recognized as safe and effective "for use in lethal injection." (AR 20.)

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manufacturer's product has been used "to a material extent or for a material time." 21 U.S.C. § 321(p)(2). If it complies with the monograph, a particular company's version of a drug is generally recognized as safe and effective regardless of how long it has been marketed. FDA's reference to a recent U.S. marketing start date for the disputed drugs therefore does not automatically establish that they are "new drugs." (AR 21.) Furthermore, FDA's reference to a domestic start date does not address foreign marketing, which also is relevant to the "material extent" and "material time" requirement. *See* 21 C.F.R. §§ 330.14(a), (b). FDA's exclusive focus on domestic marketing information cannot establish that the disputed drugs are "new drugs."

When a statutory interpretation leads inevitably to an agency inquiry this outlandish, a court should step back from the legal intricacies and consider the interpretation with common sense. It defies common sense to suggest that there might be any studies assessing a drug's safety and effectiveness "for use in lethal injection." (AR 20.) *Cf. Heckler v. Chaney*, 470 U.S. 821, 827 (1985) (referring to "the implausible result that the FDA is required to exercise its enforcement power to ensure that States only use drugs that are 'safe and effective' for human execution"). "Safety" is a term of art under the FFDCA meaning that a drug's "therapeutic benefit" outweighs its potential for "inflicting death or physical injury." *Rutherford*, 442 U.S. at 555-56. A study could never establish that a lethal injection drug satisfies that definition, given that the purpose of the drug is to induce death. In addition, for obvious ethical reasons, a drug could not possibly be studied for its "effectiveness" in causing death through lethal injection. *See, e.g.*, 21 C.F.R. part 50 ("Protection of Human Subjects").

The practical consequences of a statutory interpretation can speak volumes about its validity. In compelling a search for medical studies regarding the safety and effectiveness of a death penalty agent, FDA's statutory interpretation leads to a "'result so bizarre that Congress could not have intended it.'" *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 399 (5th Cir. 2008) (quoting *Johnson v. Sawyer*, 120 F.3d 1307, 1319 (5th Cir. 1997)). That is a sufficient basis for rejecting FDA's interpretation. *See, e.g.*, *Pub. Citizen v. U.S. Dep't of Justice*, 491 U.S. 440, 454-55 (1989); *cf. Rutherford*, 442 U.S. at 522 (exception to statutory requirement can be implied to prevent absurd results).

B. FDA's Statutory Interpretation Amounts To a Federal Product Ban That Conflicts With Congress's Intent To Defer To State Methods For Implementing Capital Sentences

FDA's statutory interpretation amounts to a federal ban of thiopental sodium for purposes of lethal injection, because no one would ever conduct the studies necessary for the FFDCA to permit that use.[22] It therefore is not surprising that FDA has stated categorically that "[s]odium thiopental is unlawful to import for purposes of lethal injection, and that applies to all states who intend to use it for that purpose."[23]

This federal product ban conflicts with Congress's intent, expressed in other statutes, that the federal government should not interfere with state methods for implementing capital sentences. For eighty years, Congress has insisted that the federal government "shall supervise implementation of [federal capital] sentence[s] in the manner prescribed by the *State* in which the sentence is imposed." 18 U.S.C. § 3596(a) (emphasis added).[24] The congressional deference to state-law procedures in federal

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[22] Under FDA's interpretation, thiopental sodium would inevitably be a "new drug," because any label would "suggest" a lethal injection use, and no studies could ever establish general recognition of safety and effectiveness for lethal injection. And without such studies, FDA also would inevitably refuse approval for that use.

[23] *Compare* Second Amended Complaint ¶ 38 (dkt. # 36) *with* Amended Answer ¶ 37 (dkt. # 47).

[24] The current statute requiring deference to state law is a newer version of a substantially similar one that Congress enacted in 1937 (the year before Congress enacted the FFDCA). Act of June 19, 1937, 50 Stat. 304 (originally codified at 18 U.S.C. § 542; recodified at 18 U.S.C. § 3566 (1948); repealed 1984). The 1937 statute (50 Stat. 304) also provided that "[t]he manner of inflicting the punishment of death shall be the manner prescribed by the laws of the State within which the sentence is imposed."

sentences is so complete that the federal government cannot impose a capital sentence at all in a state where the death penalty is illegal under state law. 18 U.S.C. § 3596(a).[25]

It is well established that several federal statutes addressing similar subjects should be construed harmoniously to the extent possible. *See, e.g.*, *Murphy v. Penn Higher Educ. Assistance Agency & Educ. Credit Mgmt. Corp.*, 282 F.3d 868, 872 (5th Cir. 2002). Following that canon, the Court should construe the broad FFDCA "new drug" provisions at issue (enacted in 1938) together with the original version of the federal capital sentencing statute (enacted the year before, by the very same 75th Congress). The Court also should construe the FFDCA together with the capital sentencing statute's later incarnation in 18 U.S.C. § 3596 (enacted in 1994). The implications of a statute such as the FFDCA may be "'altered by the implications of a later statute,'" and "[t]his is particularly so where the scope of the earlier statute is broad but the subsequent statute[ ] more specifically address[es] the topic at hand." The "'specific policy embodied in [the] later federal statute should control . . . construction of the [earlier] statute, even though it ha[s] not been expressly amended.'" *FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120, 143 (2000) (citations omitted).

The foregoing interpretive approach compels a construction of the FFDCA permitting use of thiopental sodium for lethal injection if a state-law procedure authorizes

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[25] Under those circumstances, the prisoner must be transferred to a second state, where the federal execution will proceed in accordance with the second state's procedures. *Id*.; *United States v. Sampson*, 300 F. Supp. 2d 278, 280-81 (D. Mass. 2004) (federal law precluded execution in Massachusetts because state law did not permit capital punishment).

or requires it. *First*, the Court should reject a statutory interpretation that would ban a product that Congress has indicated, in other statutes, should be available. For example, in *Brown & Williamson*, the Supreme Court rejected an FDA interpretation of the FFDCA that would inevitably lead to a prohibition on tobacco products. 529 U.S. at 137. The Supreme Court held that the product ban inherent in FDA's interpretation conflicted with congressional intent, because other later statutes permitted tobacco use. *Id*. at 137, 143-44. The product ban inherent in FDA's interpretation here similarly conflicts with the congressional intent (expressed in other statutes) not to interfere with states' capital sentencing processes (including their use of lethal injection drugs).

Second, the federalism principles at work in this case are very similar to those in a federal preemption analysis, in which a court determines congressional intent by considering a statute's potential to displace state law. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). In situations like this one, in which a federal statute might impinge upon a core state function, there is a "presumption *against* preemption." *Franks Inv. Co. v. Union Pac. R.R. Co*., 593 F.3d 404, 407 (5th Cir. 2010) (emphasis added). The Supreme Court has specifically applied the presumption against preemption in a case involving FDA's regulation of drug labeling, because of "respect for the States as 'independent sovereigns in our federal system.'" *Wyeth*, 555 U.S. at 565 n.3 (citing *Medtronic*, 518 U.S. at 485). This Court should apply a similar federalism-based presumption here and reject FDA's interpretation, holding that Congress did not intend to interfere with state-law execution procedures by banning the drugs at issue.

IV. THE COURT SHOULD NOT DEFER TO FDA'S STATUTORY AND REGULATORY INTERPRETATIONS

A. The Court Should Not Defer To FDA's Interpretation Of the Regulatory Exemption For "Law Enforcement" Use

The Court should not defer to FDA's interpretation of the regulatory exemption for "law enforcement" use set forth in 21 C.F.R. § 201.125. Under the standard set forth in *Auer v. Robbins*, 519 U.S. 452, 461-62 (1997), deference is due to "an agency's interpretation of its own *ambiguous* regulation, unless that interpretation is 'plainly erroneous or inconsistent with the regulation' or 'there is reason to suspect that the agency's interpretation does not reflect the agency's fair and considered judgment on the matter in question.'" *Knapp v. U.S. Dept. of Agric.*, 796 F.3d 445, 454 (5th Cir. 2015) (emphasis added) (citations omitted). No such deference is due to an agency's interpretation of an *unambiguous* regulation. *See, e.g., Moore v. Hannon Food Serv., Inc.*, 317 F.3d 489, 495, 496 (5th Cir. 2003). The court may still decide to consider FDA's interpretation of an unambiguous regulation under the doctrine announced in *Skidmore v Swift & Co*. 323 U.S. 134, 140 (1944), in which a court may give an agency interpretation "respect" that is "proportional to its 'power to persuade.'" *United States v. Mead Corp*., 533 U.S. 218, 235 (2001) (citation omitted); *Texas Clinical Labs, Inc. v. Sebelius*, 612 F.3d 771, 776 (5th Cir. 2010). However, "*Skidmore* analysis is of limited value in interpreting regulations, given that it stops short of requiring deference and is likely to be invoked only when a court has already found the regulation to be unambiguous." *Moore*, 317 F.3d at 497 n.14.

Here no deference is due under *Auer*, because the regulation is unambiguous. The critical regulatory term "law enforcement" has a straightforward meaning. That term is not ambiguous simply because it is broad, or because it may be applied in situations not contemplated by FDA when it promulgated the regulation. *See, e.g.*, *PGA Tour, Inc. v. Martin*, 532 U.S. 661, 689 (2001) ("'[T]he fact that a statute can be applied in situations not expressly anticipated by Congress does not demonstrate ambiguity. It demonstrates breadth.'" (citation omitted)). In addition, the provision's straightforward syntax and punctuation reinforce its unambiguous application here. *See supra* at 14.[26] The plain meaning of the regulation encompasses the disputed drugs. The Court therefore should reject FDA's interpretation. Even if it were viewed through the lens of *Skidmore*, FDA's interpretation lacks the "power to persuade." *Moore*, 317 F.3d at 497.

B. The Court Should Not Defer To FDA's Statutory Interpretations

1. The Two-Part *Chevron* Deference Doctrine Does Not Apply To the Statutory Interpretations in FDA's Import Refusal Decision

The deference doctrine announced in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc*., 467 U.S. 837 (1984) applies to statutory interpretations underlying relatively formal agency actions such as federal regulations. *Chevron* established a two-step framework. The first provides that if "Congress has directly spoken to the precise question at issue," a court does not defer and gives effect to the unambiguously expressed intent of Congress. 467 U.S. at 842-43. If Congress "has not directly addressed the

[26] No *Auer* deference would be due even if the regulation were ambiguous, because FDA's interpretation is plainly erroneous and inconsistent with the regulation.

precise question at issue," a court reaches the framework's second step, under which the court defers to the agency's statutory interpretation if it is "reasonable." *Id*. at 843-44.

In *Mead*, 533 U.S. 218, the Supreme Court held that the *Chevron* framework does not apply at all to agency decisions lacking the formality and other characteristics signifying that the agency acted under a delegation from Congress meriting judicial deference. *Mead* held that when courts review such less formal actions, the *Skidmore* doctrine (described above) applies instead of the *Chevron* framework. *Id*. at 230-31, 235.

Mead's specific holding was that the *Chevron* framework did not apply to a legal ruling by the Customs Service applying the federal tariff statute to a particular import. *Id*. at 231-34. The *Mead* import ruling is directly analogous to FDA's refusal decision, which similarly applied a federal statute (the FFDCA) to a particular import. The following chart illustrates the striking parallel between the *Mead* import ruling and FDA's refusal decision, confirming that the *Chevron* framework does not apply to the FDA statutory interpretations at issue in this case:

***MEAD* CUSTOMS IMPORT RULING**	**FDA IMPORT REFUSAL DECISION**
Customs rulings apply law to a specific set of facts regarding a specific imported product, are binding only with respect to that particular imported product or identical duplicate, and are not binding on third parties. 533 U.S. at 222 n.1, 223, 233.	FDA import refusal decisions apply law to a specific set of facts regarding a specific imported product, are binding only with respect to that particular product, and are not binding on third parties.[27]

[27] 21 U.S.C. § 381(a) (describing refusal of admission of "an article"); 21 C.F.R. § 1.94 (describing hearing regarding refusal of an imported article); FDA Regulatory Procedures Manual, ¶ 9-3-2 (describing FDA import decision-making process for a specific imported article).

***MEAD* CUSTOMS IMPORT RULING**	**FDA IMPORT REFUSAL DECISION**
Customs rulings are not subject to *Chevron* analysis because they are "churned out at a rate of 10,000 a year at [Customs'] 46 scattered offices." 533 U.S. at 233. Any of 46 ports or Customs Headquarters may issue a ruling. *Id*. at 224.	The Acting Director of FDA's Southwest Import District Office issued the refusal decision here. (AR 28, 229.) FDA issued more than 66,000 refusal decisions from Fiscal Year 2014 through June 2017. Any of FDA's 20 District Offices or FDA Headquarters may issue a refusal decision. The District Offices work in conjunction with Customs at the ports within their jurisdictions.[28]
Customs rulings are not the product of a formal process, which is pertinent, though not dispositive, for *Chevron* applicability. 533 U.S. at 231.	The FDA hearing procedure for refusals is an "informal meeting[ ] with the district" office.[29]
Most Customs rulings have little or no reasoning (although a few such as the one in *Mead* have detailed reasoning). 533 U.S. at 244.	Most FDA refusal decisions have little or no reasoning (although a few such as the one at issue in this case have detailed reasoning).[30]
Customs rulings are the official position of the agency and binding unless revoked. 533 U.S. at 222.	FDA refusal decisions are the official position of the agency and are binding unless revoked.[31]

[28] FDA Import Refusal Report, Import Refusal Data Files (FY 2014-Present), *available at* https://www.accessdata.fda.gov/scripts/importrefusals/; 21 C.F.R. §§ 1.83, 1.94 (describing hearing on refusal by Director of District Office); FDA, ORA Offices and Divisions, *available at* https://www.fda.gov/aboutfda/centersoffices/officeofglobalregulatoryoperationsandpolicy/ora/ucm135269.htm (describing 20 District Offices); FDA Regulatory Procedures Manual, *available at* https://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074300.pdf, at ¶ 9-1-4, (describing coordination between Customs and FDA).

[29] FDA Investigations Operations Manual, ¶ 6.2.7.1, *available at* https://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM123512.pdf; *see also* FDA Regulatory Procedures Manual, ¶ 9-1-5 (evidence in refusal hearing can be introduced by telephone, fax, mail, or email, and does not need to be introduced in person).

[30] (*See* AR 5-28.)

[31] 21 U.S.C. § 381(a) (requiring destruction or exportation of any "article refused admission"); Amended Answer (dkt. # 47), ¶ 61(admitting that refusal decision was FDA's final determination on the import); FDA Regulatory Procedures Manual, ¶ 9-1-5

2. The Court Should Not Accord *Skidmore* "Respect" to FDA's Statutory Interpretations

Although the *Skidmore* doctrine applies to less formal actions such as this one, courts do not accord *Skidmore* "respect" to an agency interpretation if the statute is unambiguous. That is because an agency interpretation that conflicts with the statute is unpersuasive, and an agency interpretation that is consistent with the statute is unnecessary to consider. *Catskill Mountains Chapter of Trout Unlimited, Inc. v. EPA*, 846 F.3d 492, 509, 510 n.19 & n.20 (2d Cir. 2017); *see also Nickell v. Beau View of Biloxi, LLC*, 636 F.3d 752, 755 (5th Cir. 2011) ("[W]e do not examine sources of meaning external to the statute when the statutory language is clear.").

Here no *Skidmore* "respect" is due, because the statute is unambiguous. The critical statutory terms at issue — e.g., "prescribed, recommended, or suggested" — are broad, but they are not ambiguous. As explained *supra* at 39, breadth is not the same thing as ambiguity. *See, e.g.*, *PGA Tour*, 532 U.S. at 689 (distinguishing "breadth" from "ambiguity"); *Diamond v. Chakrabarty*, 447 U.S. 303, 315 (1980) (same). The plain and ordinary meaning of the unambiguous statutory terms compels rejecting FDA's interpretation. *See supra* at 24-29.[32]

(describing destruction or exportation following refusal decision); FDA Regulatory Procedures Manual, ¶ 9-10-5 (discussing permissive appeal of refusal decision).

[32] For the same reason, no deference would be due even if the *Chevron* framework applied. The Court would need to stop its analysis at *Chevron* step one because Congress has directly spoken to the precise questions at issue.

Furthermore, no *Skidmore* "respect" would be due even if the statute were ambiguous. *Skidmore* respect is proportional to the persuasiveness of the agency's interpretation. *Mead*, 533 U.S. at 235. We explain above why FDA's interpretation is wholly unpersuasive. No *Skidmore* respect is due to an unpersuasive agency interpretation. *Vance v. Ball State Univ.*, 133 S. Ct. 2434, 2443 n.4 (2013).[33]

C. The Statute's Reference to the "Appearance" of a Violation Does Not Change the Foregoing Deference Analysis

The refusal decision asserts that a court should defer to its statutory and regulatory interpretations because the FFDCA empowers the agency to refuse imports "[i]f it *appears* from the examination of . . . samples or otherwise that . . . [an] article is . . . misbranded, or in violation of [21 U.S.C. § 355]." 21 U.S.C. § 381(a) (emphasis added). (AR 6-7.) The Court should hold that this statutory reference to the "appear[ance]" of a violation does not change the foregoing deference analysis (under which no deference is due).

First, this case presents only pure questions of law for resolution.[34] By contrast, the statute is arguably referring only to a *factual or evidentiary* determination in

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[33] In addition, because FDA's statutory interpretation is not even reasonable for the reasons explained above, no *Chevron* step two deference would be due even if the *Chevron* framework applied.

[34] The parties are presenting the merits of this case for resolution on cross-motions for summary judgment, thereby confirming that there are no material disputed facts and that the only disputed issues are legal ones. Fed. R. Civ. P. 56(a). Summary judgment is virtually always the proper mechanism for adjudicating the merits of Administrative Procedure Act cases, because in such cases a court "'has the function of determining whether the administrative action is consistent with the law — that and no more.'" *Girling Health Care, Inc. v. Shalala*, 85 F.3d 211, 214-15 (5th Cir. 1996) (citation omitted). "[W]hen a party seeks review of agency action under the APA, the district

addressing the "appear[ance]" of a violation "from the *examination* of . . . samples or otherwise." 21 U.S.C. § 381(a) (emphasis added). Every one of the court decisions cited in the refusal decision addresses the "appearance" standard in a factual or evidentiary context — giving FDA some leeway from judicial second-guessing when the agency resolves disputed facts in import decisions.[35] This case is entirely different, because the Court has pure questions of law before it for decision (not disputed facts).[36]

Second, even assuming *arguendo* that the statute's "appearance" language required judicial deference regarding a pure legal question, FDA has no basis for asserting that that language establishes a *different* degree of deference (or "respect") than that required by the generally-applicable doctrines discussed above (i.e., *Chevron* and *Skidmore*). The refusal decision cites no authority suggesting that the statute's

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judge sits as an appellate tribunal," reviewing the agency's action on a fixed administrative record "as a matter of law." *Ware v. U.S. Fed. Highway Admin.*, No. CV H-11-0848, 2016 WL 1244978, at *5 (S.D. Tex. Mar. 30, 2016) (internal citations and quotations omitted).

[35] For example, the only cited Fifth Circuit case states that FDA can refuse imported products "when the government lacks the ability to prove a violation . . . by a *preponderance of the evidence*," but the court *does not* accord deference to FDA in a ruling on a question of law. *United States v. Food, 2,998 Cases*, 64 F.3d 984, 992, 987 n.5 (5th Cir. 1995) (emphasis added). Two other cited cases predate *Chevron* and similarly address evidentiary issues. *See Goodwin v. United States*, 371 F Supp. 433, 436 (S.D. Cal. 1972) (addressing evidence of food contamination); *Sugarman v. Forbragd*, 267 F. Supp. 817, 824 (N.D. Cal. 1967) (addressing evidence regarding condition of food). Another pre-*Chevron* case ruled for FDA on an evidentiary basis, assuming that the importer's legal interpretation was correct. *See Cont'l Seafoods, Inc. v. Schweiker*, 674 F.2d 38, 43 (D.C. Cir. 1982). The remaining case does not discuss decision-making under 21 U.S.C. § 381 at all. *K&K Merch. Grp., Inc. v. Shalala*, No. 95 Civ. 10082, 1996 WL 183023 (S.D.N.Y. April 17, 1996).

[36] The FDA refusal decision erroneously asserts that the parties have a factual dispute over the disputed drugs' labels. (AR 7 n.3.) The parties do not dispute what the labels say. The parties only dispute the legal conclusions arising from the labels.

"appearance" language changes these generally-applicable doctrines when the agency interprets statutes and regulations in a decision regarding admissibility of an import. Under those doctrines, no deference is due.

CONCLUSION

The Court should grant TDCJ's motion for summary judgment and order the relief requested therein.

Respectfully submitted,

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